

LOCHT et al -- Serial No.: 08/765,287

Rejections Under 35 USC 103

Claims 1-15, 18-22, 27-30 and 39 stand rejected under 35 USC 103(a) over Loosmore et al in view of Menozzi et al. Claims 34 and 35 stand rejected under 35 USC 103(a) over Loosmore et al in view of Menozzi et al and Locht et al. The rejections are traversed for the reasons that follow.

The Examiner contends that Loosmore et al teach fusion proteins comprising an amino acid sequence from Fha fused to an amino acid sequence from a protein distinct from Fha. The Examiner makes specific reference to the gene fusions Fhap/TOX, Fahp/PRN and TOXp/Fha, described in column 5, lines 20-58, to support his/her position.

Applicants respectfully submit that these gene fusions do not code in any way for "fusion proteins comprising an amino acid sequence from Fha fused to an amino acid sequence from a protein distinct from Fha". Indeed, as clearly explained in the paragraphs cited by the Examiner, these fusions were obtained "by fusing the promoters with the structural genes at the ATG start codon of the structural gene" (column 4, lines 34-36). The next sentence then specifies that "[s]uch fusions result in a native but autologous promoter, and a structural gene with its natural signal sequence" (emphasis added).

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Attention is directed to the fact that, in the names of the gene fusions mentioned above, the letter "p" stands for "promoter". For example, Fhap/TOX designates a fusion between the Fha promoter and the TOX coding sequence.

Applicants believe that the Examiner may be suffering some confusion between a nucleotide sequence and an amino acid sequence in the interpretation of the specification of EP 0 453 216. Indeed, the fusions described by Loosmore et al comprise a nucleotide sequence from the Fha gene (i.e., the promoter sequence), and a nucleotide sequence from a gene heterologous thereto (i.e., the sequence encoding a structural gene such as TOX). However, as described unambiguously in the application, the gene fusions taught by Loosmore et al do not encode a fusion protein comprising an amino acid sequence from Fha fused to an amino acid sequence from a protein distinct from Fha.

Applicants acknowledge that Menozzi et al teach that the Fha protein is able to interact with heparin. However, one skilled in the art reading this article and the patent application by Loosmore et al would not have arrived at the claimed invention, since the Loosmore et al reference is not relevant, for the reasons given above.

The rejection of claims 34 and 35 over Loosmore et al in view of Menozzi et al and Locht et al is also traversed

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since there is nothing in Locht et al that would have suggested making fusion proteins with an Fha moiety.

Reconsideration is requested.

Rejection Under 35 USC 102(e)

Claims 40-41 stand rejected under 35 USC 102(e) as anticipated by Relman et al. The rejection is traversed.

Claims 40 and 41 relate to bacterial cells other than *Bordetella* and transformed by a recombinant DNA comprising a sequence (1) heterologous to Fha of *Bordetella*, said sequence (1) being fused in the same reading frame with a sequence (2) placed upstream from said sequence (1), said sequence (2) coding for at least the N-terminal region of Fha. The fusion encoded by the fusion gene present in the cells of claims 40 and 41 hence exhibits an N-terminal Fha moiety and a C-terminal moiety heterologous to Fha.

The Examiner refers to column 9 of Relman et al which discloses Fha B fusion proteins. Applicants refer to the same column, especially lines 45-59. This paragraph indeed discloses fusion proteins between part of the Fha and part of the phage MS2 RNA polymerase. However, contrary to the fusion recited in claim 40, these fusion proteins have an N-terminal moiety constituted by the "first 98 amino acids of the phage M32 RNA polymerase" and a C-terminal moiety

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consisting of Fha C-terminal fragment. The fusion proteins disclosed by Relman et al have been made by cloning portions of the Fha B ORF into the expression vector pEX 34 (see column 9, lines 45-46). Since these fusions have been made to confirm the absence of a translational STOP codon in various regions of the ORF, it can be understood that the Fha moiety is C-terminal.

In view of the above, reconsideration is requested.

This application is submitted to be in condition for allowance and a Notice to that effect is requested.

Respectfully submitted,

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